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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,331

02/23/2004

Lars Boerger

BD-001-US

8711

50530

7590

01/12/2009

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

01/12/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/784,331	<b>Applicant(s)</b> BOERGER ET AL.	
	<b>Examiner</b> Carlos A. Azpuru	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-6,9,10 and 13-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 9-10 and 13-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of the amendment filed 09/27/2008.

The rejection under 35 USC 112, first paragraph is withdrawn in view of applicant's amendment.

The following rejection is maintained in this action:

Claims 1, 3-5, 9, 10, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Buscemi et al (US Patent No. 5,500,013)

Buscemi et al disclose a device for implanting into the vasculature comprising a biodegradable matrix, at least one drug, and the device having a ring-like structure capable of degrading (see Abstract; col. 12, lines 47-67; col. 13, lines 1-13; Figures 1 and 3). Specific biodegradable matrix materials are found at col. 4, line 55 and col. 6, lines 10-37. Drugs disclosed for incorporation into the matrix are found at col. 12, lines 59-67; col. 13, lines 1-13. These include particle forms of the bioactive (microcapsules) at col. 10, lines 61-64, and additionally meet the limitation of a drug being incorporated into the particles. Anti-inflammatories are specifically recited at col. 13, lines 4 and 5. Mechanical expansion is disclosed at col. 5, lines 61-64. Gluing the device to the vessel wall is disclosed at col. 3, lines 1-4. The instant claims are anticipated by Buscemi et al.

***Response to Arguments***

Applicant's arguments filed 09/27/2008 have been fully considered but they are not persuasive.

Applicant contends at page 9, third paragraph, that Buscemi et al does not anticipate the instant invention contending that the microcapsules of Buscemi et al are not "incorporated particles". Applicant attempts to distinguish the microcapsules, however applicant failed to note that they are also art recognized as belonging to the general class of microparticles. Further, applicant tries to distinguish by adding that the particles of Buscemi et al are merely containers for other materials, and are composed of a list of materials. However, applicant does not point out that Buscemi et al form their microparticles from polymers on that same list. Further, applicant's claim language does not exclude the particles from carrying anything else.

Applicant further attempts to distinguish the claimed stent from that of Buscemi et al by pointing out the differences in intended use. Specifically, applicant states that the structural support provided by Buscemi et al differentiates it from the claimed device which is merely a drug delivery system. However, this intended or structural difference is not excluded by applicant's claims. Further, Buscemi et al disclose a stent which can provide both a structural support and drug delivery. This is not a patentable difference.

Neither argument is persuasive, and the rejection under 35 USC 102(b) over Buscemi et al is maintained.

The following is a new rejection of the claims:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6, 9-10 and 13-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended claim 1 to contain a Markush Group of materials used in producing the claimed particles. However, many of these appear to be coextensive. For example, polylactides as well as several of the other polymers are polyesters. Hydroxyapatite is listed twice. Applicant also lists cement and bioglass, both of which may be coextensive with hydroxyapatite and some of the other listed compounds. Also which cements and resins are contemplated. Because it is unclear as to the metes and bounds of the invention, the claims are considered indefinite.

Claim 5 sets out both “synthetic” and “genetically engineered” proteins. genetically engineered proteins would tend to be considered “synthetic.” As such, the metes and bounds of the claim are indefinite.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1615

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